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Cognitive behavioural therapy for psychosis: rationale and protocol for a systematic review and meta-analysis

Short title: CBT for psychosis review.

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ABSTRACT

Background: Cognitive behavioural therapy (CBT) is a recommended treatment for people with psychosis, with meta-analyses showing important benefits when compared to treatment as usual (TAU). However, there has been growing debate as to whether CBT has specific benefits over and above those attributable to less intensive psychosocial interventions, such as befriending and supportive counselling. Recent meta-analyses examining this question have suffered from various difficulties including potential bias and error. After detailing these problems, we present a protocol for a new review.

Methods and design: The Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, EMBASE, previous reviews and online trial registers will be systematically searched for randomised trials examining the efficacy and safety of CBT for psychosis, when compared to (a) TAU and (b) other psychosocial treatments. Primary outcomes are symptomatic change and numbers achieving clinically significant improvement. Secondary outcomes include adverse effects, change in target complaint, subjectively defined recovery and relapse.

Discussion: This review will provide service users, relatives and policy-makers with a comprehensive and up-to-date assessment of the efficacy and safety of CBT for psychosis. Advance publication and peer-review of hypotheses and methods should maximise transparency, enhancing the reliability and quality of the findings.

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INTRODUCTION

Cognitive behavioural therapy (CBTp) is a recommended treatment for people with psychosis, with numerous single-blind studies demonstrating superiority to treatment as usual in relation to symptom reduction and other domains (Wykes, Steel, Everitt and Tarrier, 2008). However there has been some debate recently as to whether CBTp has specific benefits over and above those attributable to other psychosocial interventions, such as befriending, supportive counselling and psychoeducation. Although several recent meta-analyses have attempted to assess CBTp efficacy in well-controlled trials, they have each suffered from various difficulties which make their results difficult to interpret. This means service users, providers and policy-makers do not have access to accurate information on CBTp's efficacy and adverse effects – hence the need for a new review.

Systematic reviews and meta-analyses are not immune to bias, and they do not always ask the right questions. Advance registration and peer-review of hypotheses, scope and methodology is one way of minimising these risks (Stewart, Moher and Shekelle, 2012). Before outlining our protocol, it is necessary to outline in some detail the range of problems that we and others have identified in these previous reviews.

Previous meta-analyses

Lynch et al (Lynch, Laws and McKenna, 2010)

Lynch et al examined whether CBT had a specific benefit over other psychosocial interventions in relation to overall psychotic symptoms, as well as symptom subgroups. They pooled data from 9 studies and concluded CBT has no effect, or that any effect it appeared to have was entirely attributable to bias introduced by use of non-blind ratings in some trials. They also examined relapse rates, but this time included trials utilising a treatment as usual control, and again found no effect. However their analysis and interpretation has encountered heavy criticism for various reasons (Kingdon, 2010; Lincoln, 2010), including non-adherence to generally accepted systematic review guidelines:

“Because many [meta-analyses] have failed to report procedures in a transparent way that enables readers to assess strengths and weaknesses, a group of researchers developed the QUORUM guidelines.... These list 19 major criteria which are deemed essential for transparent reporting of the method and results in a systematic review...Lynch et al. (2009) only comply with five of these.” (Lincoln, 2010)

When we attempted to replicate the Lynch review, we encountered several other problems. To begin with, their selection and exclusion of trials lacked consistency. For example, Lynch et al excluded a well-conducted CBT-favourable single-blind study (Jackson et al., 2008) because “*patients were not all schizophrenic*”, noting more than 20% (21-33% in this case) had a diagnosis of affective psychosis. However they included 2 other studies, one equivocal (Lewis et al., 2002) and one favourable to CBT (Drury, Birchwood, Cochrane and MacMillan, 1996), where at most 60% were given a schizophrenia diagnosis. Another CBT-favourable study (Penn et al., 2009) was simply omitted, despite it almost certainly being available to the authors at the time of their review.

Lynch et al also did not consider the impact of treatment duration on efficacy estimates, nor did their control treatments always meet their definition of ‘non-specific treatments’. For

example, participants in the largest of the included trials received on average only 8.6 hours of CBT over a 5-week period (Lewis et al., 2002), which is considerably less than the 16 hours recommended by NICE (National Institute for Clinical Excellence, 2009). Participants in the second largest trial received only 8 weeks of group CBT or group psychoeducation (Bechdolf et al., 2004). Importantly, ‘psychoeducation’ in this trial involved discussion of models of psychosis and use of strategies such as relapse prevention, formulation and guided discovery – each of which are generally thought to be key components of CBT for psychosis (Morrison and Barratt, 2010).

Lynch et al also excluded CBT-favourable data from the largest study of CBTp to date (N=422) because it used readmission as a proxy measure of relapse (Turkington et al., 2006), arguing that any CBT-favourable reduction in readmission rates would reflect a large-scale ‘Hawthorne effect’ – i.e., a clinician who knows a patient is receiving CBT in the community will therefore be less likely to admit them to hospital, regardless of the patient’s actual needs. They suggested that assessments of relapse by study investigators would be more objective. However their assumption was not supported with evidence; they did not examine whether there was any difference between relapse and readmission figures in studies which measured both outcomes, nor did they assess whether reduced readmission for those receiving CBT only occurred, if it occurred at all, during the treatment rather than follow-up phase (i.e., when putative Hawthorne effects would likely diminish). They also applied their own criteria inconsistently, in that they included readmission data from a study (Tarrier et al., 1999) which they identified as unfavourable to CBT.

Lynch et al also claimed that rater bias has led to inflated estimates of CBTp efficacy, based on the observation that two small (N=37-40) non-blind studies (Drury et al., 1996; Pinto, La Pia, Mannella, Domenico and DeSimone, 1999) reported relatively larger effects than those employing rater-masking. Although non-blindness is a well-known source of bias (Schulz, Chalmers, Hayes and Altman, 1995), Lynch et al did not consider alternative explanations for the differences, such as publication bias, small sample effects, regression to the mean, exclusion of participants from the analysis (Drury et al., 1996), or the additional interventions received by the CBT group participants (Drury et al., 1996; Pinto et al., 1999). Indeed, two blind studies reported even larger effects than the non-blind studies, but these were excluded by Lynch et al because they were too small (Levine, Barak and Granek, 1998; Turkington and Kingdon, 2000). Their exclusion of 2 larger blind studies (Jackson et al., 2008; Penn et al., 2009), each reporting moderate effects, also contributed to the impression of reduced efficacy in the blind trials.

There are other problems with Lynch et al’s review, including their protocol not being published in advance, their failure to analyse all usable data from each study, or carry out an intention-to-treat analysis, or consider response rates or follow-up data (Kingdon, 2010), or report a full risk of bias assessment (Higgins et al., 2011a). They also include a non-CBT study in their relapse analysis, as pointed out by both Kingdon and Lincoln (Kingdon, 2010; Lincoln, 2010). Unfortunately, the cumulative nature of these problems suggests little can be inferred from it, and that its conclusions ought to be set aside. This applies both to their assessment of efficacy, as well as their conclusion that non-blind assessments are entirely responsible for any perception of efficacy.

Newton-Howes and Wood, 2011 (Newton-Howes and Wood, 2011)

Newton-Howes and Wood present a similar analysis to Lynch et al., but only examined symptomatic change. They pooled data from 9 studies, most of which were also analysed by Lynch et al, and also concluded CBT has no specific benefit. However, as with Lynch et al, attempting to replicate the review revealed a number of issues with their study inclusion criteria and analysis of outcomes. As discussed in a commentary published with the review (Hutton, 2013), the authors did not include all available studies, did not justify exclusion of key studies, analysed baseline data for one study instead of outcome data and calculated incorrect standard deviations for another. This led to a large effect being calculated in favour of the control condition in this study, when in fact there was no difference between the groups. They did not justify their selection of outcome data for each study, and their decision-making in relation to this was hard to understand. Like Lynch et al., they did not make use of follow-up data, nor did they assess adverse effects, rates of important clinical response or the impact of treatment duration. As outlined elsewhere (Hutton, 2013), the substantive problems with this review means little can be inferred from it.

Jones et al, 2012 (Cochrane review) (Jones, Hacker, Cormac, Meaden and Irving, 2012)

Cochrane reviews are highly regarded in medicine and healthcare, and have an important influence on the health policies of many countries (Cumpton and Clark, 2004). The recently released Cochrane review of CBT for schizophrenia attempted to provide a fine-grained analysis of CBT efficacy and harms when compared to both inactive and active treatments across a range of outcomes. The authors concluded that “*Trial-based evidence suggests no clear and convincing advantage for cognitive behavioural therapy over other - and sometime much less sophisticated - therapies for people with schizophrenia.*” (Jones et al., 2012).

As with the previously examined reviews, and as with other Cochrane reviews of schizophrenia treatments (Hutton et al., 2012), we found a number of serious problems when we attempted to replicate it. To begin with, the authors made the mistake of analysing pre-therapy negative symptom and depression data from Sensky 2000 (Sensky et al., 2000) as if they were post-, with obvious implications for their conclusions. In fact, they did not present overall psychopathology data for this relatively large study at all, either at end-of-treatment or follow-up, without a reason being given. As with the other two reviews, duration of CBT received was not considered, managed or taken into account.

The author’s rationale for describing data-sets as short, medium or long-term was also unclear given follow-up data from the large 5-week Lewis trial (Lewis et al., 2002) was combined with follow-up data from trials with treatment periods lasting 5 times longer or more. Their definition of active and inactive treatments is also based on little evidence and seems hard to justify. For example, supportive counselling is variously described as ‘active’ for Penn 2009 (Penn et al., 2009) and Pinto 1999 (Pinto et al., 1999) and ‘inactive’ for Lewis 2002 (Lewis et al., 2002), meaning these studies were not combined to produce an overall estimate. Relapse data from one study was also entered incorrectly, erroneously favouring CBT (Tarrier et al., 2004). These and other problems, not detailed here for sake of brevity, suggest that this review suffers from the same quality control problems we have observed in other Cochrane Schizophrenia Group reviews (Hutton et al., 2012).

To summarise, we have shown that recent reviews of well-controlled trials of CBT for psychosis each suffer from considerable flaws. This means service users, relatives, providers and policy-makers currently have very limited information on which to base treatment decisions. A new review and meta-analysis is clearly required.

Objectives

Our main objective is to conduct a comprehensive systematic review and meta-analysis of CBT for people with a schizophrenia-spectrum diagnosis, testing the primary hypothesis that it will be significantly more effective than (a) treatment as usual and (b) other psychosocial treatments on the primary outcomes of (i) overall symptom change and (ii) rates of clinically significant improvement, at end-of-treatment and follow-up. We will also examine adverse effects, improvements in target symptoms (i.e., primary outcome in each study) and rates of relapse, readmission to hospital and deterioration. We will also examine whether there are CBT-attributable improvements across a range of secondary outcomes, including positive and negative symptoms, quality of life, functioning, subjectively defined recovery, depression and anxiety.

METHODS

Inclusion and exclusion criteria

Population

As per the recent Cochrane review (Jones et al., 2012), we will include trials where $\geq 50\%$ of participants have a diagnosis of schizophrenia, schizoaffective disorder or early psychosis, as defined by any criteria. We will not include studies where $>50\%$ participants have an established diagnosis of bipolar disorder, learning disability, psychosis secondary to a general medical condition or organic pathology, or a primary diagnosis of substance-induced psychosis. No limits will be placed on age of participants or severity or duration of illness.

Interventions and comparators

We will include all randomised controlled treatment trials of CBTp, but conduct separate analyses for CBT vs. usual treatment and CBT vs. other psychosocial treatments. For the latter, we will not make a priori judgements about whether comparator treatments are 'active' or 'inactive' or 'specific' or 'non-specific'. As argued by Lincoln (Lincoln, 2010), it is not clear whether psychodynamic therapy, psychoeducation or social skills training can be confidently described as atheoretical (Newton-Howes and Wood, 2011) or nonspecific (Lynch et al., 2010). We will instead compare CBT to comparator treatments individually, pooling trials where the same or very similar treatment is used as a control, as well as in combination.

Study design

Only studies utilising concealed and random allocation to treatment conditions will be included. Observational studies, uncontrolled case series studies, crossover trials and cohort studies will be excluded.

Outcomes

Our primary outcomes are overall symptom change and rates of clinically significant improvement at end-of-treatment and at follow-up. Eligible reports must therefore provide continuous and / or binary post-treatment data on a valid and reliable measure of overall psychotic symptoms.

We will also assess change in target symptom (i.e., primary outcome of each trial), adverse effects, relapse, readmission and deterioration. Other secondary outcomes of interest will

include positive symptoms, negative symptom, general psychopathology, acceptability (as indexed by the number leaving early for any reason), quality of life, functioning, subjectively defined recovery, depression, anxiety, suicidality, hopelessness, employment and death. We will also examine whether CBT has any effect on hypothesised mechanisms of change, such as self-esteem, core beliefs (schemas), appraisals and safety-seeking behaviours. For all outcomes, we will examine end of treatment and follow-up. Eligible reports must therefore provide usable continuous or binary data relating to one or more of these outcomes.

Search strategy

We will search through references of the reviews mentioned above, as well as the comprehensive Wykes et al review (Wykes et al., 2008). We will also search the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, EMBASE and the online clinical trials registers of the US government, European Union, World Health Organisation as well as Current Controlled Trials Ltd. Titles, abstracts and keywords will be searched in the publication databases using the following strategy:

(schizo% [exp. schizophrenia OR psychosis OR schizoaffective]) AND (trial [exp. RCT OR controlled trial OR clinical trial]) AND (cbt [exp. cognitive therapy OR behaviour therapy OR psychotherapy]).

No date limits will be placed on the search. We will ask key researchers and previous reviewers to check our final list for completeness. The main search will be carried out independently and in parallel by LW and KI.

Study selection

Titles and abstracts will be screened for relevance by LW and KI. Full-text reports of all potential studies will be accessed and eligibility will be determined by LW, KI and PH against above-mentioned criteria. Discrepancies will be discussed, and arbitration by TM sought if consensus is lacking. All decision-making will be carefully minuted, and all electronic searches will be saved on file where possible.

Data extraction

Data (no of events, means, SDs) from relevant studies will be extracted into pre-defined tables by PH, LW and PT. Data on study characteristics will also be extracted, and will include duration of treatment, number of sessions offered, number of arms, type of treatment offered, control condition details, diagnosis, number of centres, baseline demographics (age, gender, symptom severity at baseline), available follow-up data points used and drop-out rates at each time-point.

Not all trials will report the same data, which means we need to decide in advance our ‘data extraction hierarchy’ for our primary outcome. This should specify what data will be preferable, and what data will be used if this cannot be acquired. We decided to use the hierarchy used by a recent drug meta-analysis (Leucht, Arbter, Engel, Kissling and Davis, 2009) to define average change in overall symptoms: mean change in Positive and Negative Syndrome Scale (PANSS) total scores (Kay, Fiszbein and Opler, 1987) > mean change in Brief Psychiatric Rating Scale (BPRS) total scores (Overall and Gorham, 1962) > endpoint PANSS total scores > endpoint BPRS total scores > mean change in principal measure of

overall psychopathology used by authors > endpoint on principal measure of overall psychopathology used by authors.

We will also use Leucht et al's (2009) hierarchy for our analysis of clinically significant response: number with at least 50% reduction in PANSS total scores> number with at least 50% reduction in BPRS total scores> number with much improvement on the Clinical Global Impression-Improvement scale (CGI-I)> number with improvement as defined by the authors (usually a composite or >20-30% improvement in PANSS/BPRS scores). We will also try to acquire data on numbers achieving 11-15 and 10-point reductions in PANSS/BPRS total scores (Hermes, Sokoloff, Stroup and Rosenheck, 2012; Leucht et al., 2006).

Our analysis of adverse effects, relapse, readmission and deterioration will need to depend on available data, and we expect we will be limited by a range of idiosyncratic author definitions and measurements. We will not use estimates of numbers relapsing from studies where participants are unwell / unstable at baseline, nor will we use estimates of numbers returning to hospital from studies where participants are in hospital at baseline, as such figures are confounded by numbers recovering. For all studies, we will extract data on number of days in/out of hospital and number of days in/out of remission/recovery/stability.

Methodological quality

We will assess trial quality with the GRADE approach (Guyatt et al., 2008), and risk of bias with the Cochrane Collaboration Risk of Bias tool (Higgins et al., 2011a). This involves categorising studies as having a low, high or unclear risk of bias in the areas of selection and allocation of participants, intervention concealment, attrition and reporting. The results of this assessment will be used to inform interpretation of reported effect sizes and overall conclusions. We will endeavour to compare trial reports to original protocols, where possible, and all study authors will be contacted for missing data.

Initial assessments will be carried out independently by two researchers who are unfamiliar with the literature. Inter-rater agreement will be assessed and both sets of assessments will be provided as supplementary data in the eventual report. The overall final assessment will be produced through a review with a third researcher with knowledge of the literature. All three researchers will complete the GRADE online learning modules (<http://cebgrade.mcmaster.ca/>). All decisions will be recorded and provided as supplementary data, allowing readers to appreciate the extent of any uncertainty as well as provide greater transparency.

Data synthesis and analysis

Meta-analytic calculations

We will employ a strict intention-to-treat (ITT) analysis for dichotomous data, using the total numbers randomised to each group as the denominator in each case. We will assume those leaving early had the unchanged outcome.

For continuous outcomes, we will use summary data based on a mixed-model repeated measures imputation method when available; if not available, we expect to be restricted to using data incorporating last observation carried forward assumptions. We will only include

study data if this incorporates end-point scores from 50% or more of those who were randomised.

For binary data, we will calculate the odds ratio (OR) of the unfavourable outcome together with 95% confidence intervals, as well as the absolute risk difference. The NNT will be calculated in two ways; (1) as the inverse of the RD, as per Leucht et al (Leucht et al., 2009) and (2) as a product of the OR and a range of 'assumed control risks' (ACRs), following equations specified in section 12.5.4.3 of the Cochrane Handbook (Higgins, Green and Collaboration, 2011b). We will combine continuous data from different outcome measures to allow calculation of the standardised mean difference (SMD). We will calculate this and 95% confidence intervals (CI) using Revman or Comprehensive Meta-Analysis software, both of which use the Hedges's g adjustment for small sample bias. We will use 2-tailed hypotheses throughout, and endeavour to interpret p-values in a sensible fashion, treating probability as a dimensional rather than binary construct. We will note where results do meet the conventional criterion for significance ($p < .05$).

We will take three approaches to interpreting the clinical significance of the mean change data on continuous outcomes. First, we will see whether the average difference in PANSS/BPRS total scores is above 11-15/10 points (Hermes et al., 2012; Leucht et al., 2006). Second, we will see whether the Hedges's g effect size is, in statistical terms marginal (0.1), small (0.2), moderate (0.5), large (0.8) or very large (>0.8). Third, we will compare effect sizes to those of other established treatments.

We will use a random-effects analysis for both continuous and binary outcomes, but also carry out a fixed-effects analysis if heterogeneity is less than moderate. Moderate heterogeneity will be assumed if the I-squared statistic is 40% or more (Higgins et al., 2011b).

Subgroup analyses, sensitivity analyses and tests for publication bias

Our main subgroup analysis will involve comparing short-duration, medium-duration and long-duration CBT on the primary outcomes. We will also compare effect sizes in single-blind vs. open-label studies, and examine whether there is an effect of publication year, population (acute vs. stable, early-episode vs. chronic), or whether trials involving CBT plus an additional psychosocial treatment (CBTp+) are associated with larger effect sizes than trials of CBT alone.

If data reporting allows, we intend to carry out sensitivity analyses to explore the impact of changing assumptions about the outcome of those lost to follow-up. For example, we will examine whether the results differ if we assume those not completing the trial had an unfavourable or favourable outcome. This will allow readers to appreciate the degree of uncertainty in the estimates. We will also assess the impact of using a fixed-effects rather than random-effects analysis (but only if heterogeneity is moderate or less, defined as $I^2 \leq 40\%$), and conduct tests for publication bias (i.e., Egger test, funnel-plots etc.), but only if there is sufficient power (Ioannidis and Trikalinos, 2007).

DISCUSSION

Our proposed review will help to clarify the effectiveness and safety of CBT for people with psychosis, both in comparison to normal treatment and in comparison to other, sometimes less intensive, psychosocial interventions.

Although our familiarity with the results of older CBTp trials means our review cannot be considered truly prospective, we have yet to systematically review the results of more recent trials. In undertaking this work, advance registration of hypotheses, scope and methodology will increase transparency and minimise the risk of bias.

As we have shown, currently available reviews suffer from major flaws. This means service users, relative, providers and policy-makers currently have very limited information on which to base treatment decisions. The results of our proposed review may have important consequences for the delivery of CBT for psychosis, and will make a major contribution to the debate over efficacy. Gaps in the evidence will be highlighted, offering directions for future research.

Declaration of interest:

The authors are all involved in developing and testing psychological treatments for psychosis. They declare no financial conflicts of interests.

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